510(k) Summary

Submitted By:

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Date Summary Prepared: August 19, 2009

Device Name: Classification Name- Urological catheter and accessories
Common/Usual Name- Catheter, Urological
Proprietary Name- VaPro™ Intermittent Catheter

Predicate Device: The VaPro intermittent catheter is substantially equivalent to the following products:

Product	510(k)
Astra Tech AB Lofric® Primo™ Single Use Urinary Catheter	K050874
SpeediCath Catheter	K023254
Incare Advance/Advance Plus Intermittent Catheter	K013483

Device Description: The VaPro intermittent catheter is a hydrophilic coated single use catheter to be used as a means of managing urinary incontinence by draining urine from the bladder. The catheter comes in a protective sleeve and is offered with a protective introducer tip as a way to shield the sterile catheter from bacteria in the distal urethra during insertion. The packaging contains a vapor strip that hydrates the catheter coating which then lubricates the catheter. The outer packaging was designed to facilitate access for those with limited dexterity.

Intended Use: The VaPro intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.

Technological Characteristics: The table below summarizes the technological characteristics of the device as compared to the predicate devices.

Characteristics	VaPro Standard with Tip	Astra Tech AB Lofric® Primo™ (K050874)	Speedicath (K023254)	Incare Advance/Advance Plus (K013483)
Intended Use	The VaPro intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.	The LoFric Primo Single Use Urinary Catheter is intended for intermittent catheterization of the urethra.	The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.	Indicated for use by male, female and pediatric patients for the purpose of bladder drainage. The Catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract.
Condition of Use	Single Use	Single Use	Single Use	Single Use
Prelubricated	Yes-by water vapor hydration	Yes- by water hydration	Yes-by saline solution hydration	Yes-by hydrogel
Ready to use	Yes	Requires bursting of water sachet prior to use	Yes	Yes
End Design	Funnel	Funnel	Funnel	Funnel
Sterile	Yes	Yes	Yes	Yes
No touch design	Yes-contains sleeve	Yes – by using exterior packaging	No	Yes-contains sleeve
Lubricant	PVP Based (polyvinylpyrollidone) Coating	PVP Based (polyvinylpyrollidone) Coating	PVP Based (polyvinylpyrollidone) Coating	Hydrogel
Protective Tip	Yes	No	No	Yes

Performance Testing Conclusions:	Biocompatibility testing was performed based on the United States Food and Drug Administration Office of Device Evaluation General program Memorandum #G95-1 and ISO 10993 biocompatibility testing standards. Results indicate compliance to the standard. Product evaluation also supports device functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 20 2009

Mr. Chris Stukel
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Re: K090960
Trade/Device Name: VaPro™ Intermittent Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: August 13, 2009
Received: August 14, 2009

Dear Mr. Stukel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090960

Device Name: VaPro™ Intermittent Catheter

Indications for Use:

The VaPro intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090960